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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

JOAN DIGGS,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC, (FKA G.D. SEARLE &
CO.), Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-2900-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle"), (collectively "Defendants") and file their Answer to Plaintiff's Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the
10 specific time periods in which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
16 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
17 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
19 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,
20 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with their
22 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
23 in accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Celebrex® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
27 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
28 Complaint.

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2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including North Carolina, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States, including Florida, to be prescribed by healthcare providers who

1 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 6. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a
4 merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit
5 that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the
6 United States to be prescribed by healthcare providers who are by law authorized to prescribe
7 drugs in accordance with their approval by the FDA. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 **Response to Allegations Regarding Jurisdiction and Venue**

10 7. Defendants are without knowledge or information to form a belief as to the truth of the
11 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
12 therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount
13 in controversy exceeds \$75,000, exclusive of interests and costs.

14 8. Defendants are without knowledge or information to form a belief as to the truth of the
15 allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount
16 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims
17 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of
18 interests and costs.

19 9. Defendants are without knowledge or information to form a belief as to the allegations
20 in this paragraph of the Complaint regarding the judicial district in which the asserted claims
21 allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe
22 and effective when used in accordance with its FDA-approved prescribing information.
23 Defendants deny committing a tort in the States of California and Virginia, and deny the
24 remaining allegations in this paragraph of the Complaint.

25 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
26 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
27 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
28 Defendants admit that, during certain periods of time, Celebrex® was manufactured and

1 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
2 Celebrex® in the United States to be prescribed by healthcare providers who are by law
3 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
4 that Pfizer, Pharmacia, and Searle are registered to and do business in the State of and
5 California. Defendants state that the allegations in this paragraph of the Complaint regarding
6 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
7 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
8 the same. Defendants deny committing a tort in the States of and Virginia, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 **Response to Allegations Regarding Interdistrict Assignment**

11 11. Defendants state that this paragraph of the Complaint contains legal contentions to
12 which no response is required. To the extent that a response is deemed required, Defendants
13 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
14 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
15 Panel on Multidistrict Litigation on September 6, 2005.

16 **Response to Factual Allegations**

17 12. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
20 paragraph of the Complaint.

21 13. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical
23 condition and whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants
24 state that Celebrex® was and is safe and effective when used in accordance with its FDA-
25 approved prescribing information. Defendants state that the potential effects of Celebrex®
26 were and are adequately described in its FDA-approved prescribing information, which was at
27 all times adequate and comported with applicable standards of care and law. Defendants deny
28 the remaining allegations in this paragraph of the Complaint.

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14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information. Defendants
3 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny
4 the remaining allegations in this paragraph of the Complaint.

5 19. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
12 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
13 paragraph of the Complaint.

14 20. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny
19 the remaining allegations in this paragraph of the Complaint.

20 21. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
27 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
28 paragraph of the Complaint.

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22. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

24. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

26. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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28. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

29. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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31. Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants deny the remaining allegations in this paragraph of the Complaint.

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34. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants deny the allegations in this paragraph of the Complaint.

36. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via

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1 inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex
2 does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the
3 proper context for the remaining allegations in this paragraph of the Complaint. Defendants
4 therefore lack knowledge or information sufficient to form a belief as to the truth of such
5 allegations and, therefore, deny the same.

6 37. Defendants state that the allegations in this paragraph of the Complaint are not directed
7 towards Defendants and, therefore, no response is required. To the extent that a response is
8 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
9 allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or
10 information sufficient to form a belief as to the truth of such allegations and, therefore, deny the
11 same.

12 38. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
13 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
14 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
15 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
16 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law
18 authorized to prescribe drugs in accordance with their approval by the FDA. Plaintiff fails to
19 provide the proper context for the allegations in this paragraph of the Complaint regarding
20 “pharmaceutical researchers, scientists, and companies.” Defendants therefore lack knowledge
21 or information sufficient to form a belief as to the truth of such allegations and, therefore, deny
22 the same. Defendants deny any wrongful conduct and deny the remaining allegations in this
23 paragraph of the Complaint.

24 39. Defendants state that the Celebrex® label speaks for itself and respectfully refer the
25 Court to the Celebrex® label for its actual language and text. Any attempt to characterize the
26 Celebrex® label is denied. Defendants state that Celebrex® was and is safe and effective when
27 used in accordance with its FDA-approved prescribing information. Defendants state that the
28 potential effects of Celebrex® were and are adequately described in its FDA-approved

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1 prescribing information, which was at all times adequate and comported with applicable
2 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
3 allegations in this paragraph of the Complaint.

4 40. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex® and, therefore, deny the same. Defendants state that the referenced article and
7 website speaks for themselves and respectfully refer the Court to the article and website for
8 their actual language and text. Any attempt to characterize the article and website is denied.
9 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
10 FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that
11 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 41. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
15 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

16 42. Defendants state that Celebrex® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint, including all subparts.

22 43. Defendants state that the allegations in this paragraph of the Complaint are not directed
23 towards Defendants and, therefore, no response is required. To the extent that a response is
24 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
25 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
26 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27 44. Defendants state that the allegations in this paragraph of the Complaint are not directed
28 towards Defendants and, therefore, no response is required. To the extent that a response is

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1 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
3 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 45. Defendants state that the allegations in this paragraph of the Complaint are not directed
5 towards Defendants and, therefore, no response is required. To the extent that a response is
6 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
7 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
8 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

9 46. Defendants state that the allegations in this paragraph of the Complaint are not directed
10 towards Defendants and, therefore, no response is required. To the extent that a response is
11 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 47. Defendants state that the allegations in this paragraph of the Complaint are not directed
15 towards Defendants and, therefore, no response is required. To the extent that a response is
16 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
18 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19 48. Defendants state that the allegations in this paragraph of the Complaint are not directed
20 towards Defendants and, therefore, no response is required. To the extent that a response is
21 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
22 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
23 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

24 49. Defendants state that the allegations in this paragraph of the Complaint are not directed
25 towards Defendants and, therefore, no response is required. To the extent that a response is
26 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
27 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
28 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 50. Defendants state that the allegations in this paragraph of the Complaint are not directed
2 towards Defendants and, therefore, no response is required. To the extent that a response is
3 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
4 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
5 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

6 51. Defendants state that the allegations in this paragraph of the Complaint are not directed
7 towards Defendants and, therefore, no response is required. To the extent that a response is
8 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
9 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
10 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

11 52. Defendants state that the allegations in this paragraph of the Complaint are not directed
12 towards Defendants and, therefore, no response is required. To the extent that a response is
13 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
14 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
15 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

16 53. Defendants state that the allegations in this paragraph of the Complaint are not directed
17 towards Defendants and, therefore, no response is required. To the extent that a response is
18 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
19 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
20 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21 54. Plaintiff does not allege having used Bextra® in this Complaint. Nevertheless,
22 Defendants state that Bextra® was and is safe and effective when used in accordance with its
23 FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to
27 the letter for its actual language and text. Any attempt to characterize the letter is denied.
28 Defendants state that the remaining allegations in this paragraph of the Complaint are not

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1 directed towards Defendants and, therefore, no response is required. To the extent that a
2 response is deemed required, Defendants state that Plaintiff fails to provide the proper context
3 for the remaining allegations in this paragraph of the Complaint. Defendants therefore lack
4 sufficient information or knowledge to form a belief as to the truth of such allegations and,
5 therefore, deny the same.

6 55. Defendants state that the allegations in this paragraph of the Complaint are not directed
7 towards Defendants and, therefore, no response is required. To the extent that a response is
8 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
9 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
10 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

11 56. Defendants state that the allegations in this paragraph of the Complaint are not directed
12 towards Defendants and, therefore, no response is required. To the extent that a response is
13 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
14 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
15 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

16 57. Plaintiff does not allege having used Bextra® in this Complaint. Nevertheless,
17 Defendants state that Bextra® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
19 were and are adequately described in its FDA-approved prescribing information, which was at
20 all times adequate and comported with applicable standards of care and law. Defendants state
21 that the Bextra® label speaks for itself and respectfully refer the Court to the Bextra® label for
22 its actual language and text. Any attempt to characterize the Bextra® label is denied.
23 Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of
24 April 7, 2005. Defendants deny the remaining allegations regarding Bextra® in this paragraph
25 of the Complaint. Defendants state that the remaining allegations in this paragraph of the
26 Complaint are not directed towards Defendants and, therefore, no response is required. To the
27 extent that a response is deemed required, Defendants state that Plaintiff fails to provide the
28 proper context for the remaining allegations in this paragraph of the Complaint. Defendants

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1 therefore lack sufficient information or knowledge to form a belief as to the truth of such
2 allegations and, therefore, deny the same.

3 58. Defendants state that Celebrex® is a prescription medication which is approved by the
4 FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2)
5 for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of
6 acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of
7 adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual
8 care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing
9 spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in
10 patients two years of age and older. Defendants deny the remaining allegations in this
11 paragraph of the Complaint.

12 59. Defendants state that the Celebrex® label speaks for itself and respectfully refer the
13 Court to the Celebrex® label for its actual language and text. Any attempt to characterize the
14 Celebrex® label is denied. Defendants state that Celebrex® was and is safe and effective when
15 used in accordance with its FDA-approved prescribing information. Defendants state that the
16 potential effects of Celebrex® were and are adequately described in its FDA-approved
17 prescribing information, which was at all times adequate and comported with applicable
18 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
19 Complaint.

20 60. Defendants state that the referenced FDA Announcement speaks for itself and
21 respectfully refer the Court to the FDA Announcement for its actual language and text. Any
22 attempt to characterize the FDA Announcement is denied. Defendants state that Plaintiff fails
23 to provide the proper context for the allegations in this paragraph of the Complaint regarding
24 “all manufacturers of prescription NSAIDs,” and “over-the-counter (OTC) NSAIDs.”
25 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of
26 such allegations and, therefore, deny the same. Defendants deny any wrongful conduct and
27 deny the remaining allegations in this paragraph of the Complaint.

28

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61. Defendants state that the referenced FDA Announcement and Medication Guide speaks for themselves and respectfully refer the Court to the FDA Announcement and Medication Guide for their actual language and text. Any attempt to characterize the FDA Announcement is denied. Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding “OTC NSAIDs.” Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

63. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

65. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint, including all subparts.

66. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-

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1 approved prescribing information. Defendants state that the potential effects of Celebrex®
2 were and are adequately described in its FDA-approved prescribing information, which was at
3 all times adequate and comported with applicable standards of care and law. Defendants deny
4 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

5 68. Defendants state that this paragraph of the Complaint contains legal contentions to
6 which no response is required. To the extent that a response is deemed required, Defendants
7 deny the allegations in this paragraph of the Complaint.

8 69. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 70. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
16 deny the remaining allegations in this paragraph of the Complaint.

17 71. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 72. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 73. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 74. Defendants state that the Celebrex® label speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 75. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 76. Defendants state that the Celebrex® package insert speaks for itself and respectfully
26 refer the Court to the package insert for its actual language and text. Any attempt to
27 characterize the package insert is denied. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 77. Defendants state that the Celebrex® package insert speaks for itself and respectfully
6 refer the Court to the package insert for its actual language and text. Any attempt to
7 characterize the package insert is denied. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 78. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state
20 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
21 prescribing information. Defendants state that the potential effects of Celebrex® were and are
22 adequately described in its FDA-approved prescribing information, which was at all times
23 adequate and comported with applicable standards of care and law. Defendants deny any
24 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25 79. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex® and, therefore, deny the same. Defendants admit that, during certain periods of
28 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be

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1 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
2 with their approval by the FDA. Defendants admit that, during certain periods of time,
3 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
4 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
5 providers who are by law authorized to prescribe drugs in accordance with their approval by the
6 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
11 the Complaint.

12 80. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 81. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 82. Defendants deny any wrongful conduct and deny the remaining allegations in this
25 paragraph of the Complaint.

26 83. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 84. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
8 this paragraph of the Complaint.

9 85. Defendants state that the referenced article speaks for itself and respectfully refer the
10 Court to the article for its actual language and text. Any attempt to characterize the article is
11 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
13 this paragraph of the Complaint.

14 86. Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny the allegations in this paragraph of the Complaint.

19 87. Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 88. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA
26 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
27 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
28 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself

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1 and respectfully refer the Court to the study for its actual language and text. Any attempt to
2 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
3 the Complaint.

4 89. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants state that the
7 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court
8 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to
9 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining
10 allegations in this paragraph of the Complaint.

11 90. Defendants state that the referenced study speaks for itself and respectfully refer the
12 Court to the study for its actual language and text. Any attempt to characterize the study is
13 denied. Defendants state that the referenced article speaks for itself and respectfully refer the
14 Court to the article for its actual language and text. Any attempt to characterize the article is
15 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
16 paragraph of the Complaint.

17 91. Defendants state that the referenced Medical Officer Review speaks for itself and
18 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
19 attempt to characterize the Medical Officer Review is denied. Defendants state that the
20 referenced article speaks for itself and respectfully refer the Court to the article for its actual
21 language and text. Any attempt to characterize the article is denied. Defendants deny the
22 remaining allegations in this paragraph of the Complaint.

23 92. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 93. Defendants state that the referenced articles speak for themselves and respectfully refer
28 the Court to the articles for their actual language and text. Any attempt to characterize the

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1 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
2 refer the Court to the study for its actual language and text. Any attempt to characterize the
3 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 94. Defendants state that the referenced Medical Officer Review speaks for itself and
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
7 allegations in this paragraph of the Complaint.

8 95. Plaintiff fails to provide the proper context for the allegations concerning “Public
9 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
10 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 96. Defendants state that the referenced study speaks for itself and respectfully refer the
13 Court to the study for its actual language and text. Any attempt to characterize the study is
14 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public
15 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
16 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 97. Defendants admit that there was a clinical trial called APC. Defendants state that the
19 referenced article speaks for itself and respectfully refer the Court to the article for its actual
20 language and text. Any attempt to characterize the article is denied. Defendants deny the
21 remaining allegations in this paragraph of the Complaint.

22 98. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
23 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
24 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 99. Defendants state that the referenced Medical Officer Review speaks for itself and
27 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
28

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1 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
2 allegations in this paragraph of the Complaint.

3 100. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
4 the proper context for the allegations concerning “other Celebrex trials” contained in this
5 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
6 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
7 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state
8 that the referenced study speaks for itself and respectfully refer the Court to the study for its
9 actual language and text. Any attempt to characterize the study is denied. Defendants deny the
10 remaining allegations in this paragraph of the Complaint.

11 101. Defendants state that the referenced article speaks for itself and respectfully refer the
12 Court to the article for its actual language and text. Any attempt to characterize the article is
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 102. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
15 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
16 therefore lack sufficient information or knowledge to form a belief as to the truth of such
17 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for
18 themselves and respectfully refer the Court to the studies for their actual language and text.
19 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in
20 this paragraph of the Complaint.

21 103. Defendants state that the referenced Medical Officer Review speaks for itself and
22 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
23 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
24 allegations in this paragraph of the Complaint.

25 104. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®
26 in this paragraph of the Complaint are not directed toward Defendants, and therefore no
27 response is required. To the extent that a response is deemed required, Plaintiff fails to provide
28 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in

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1 this paragraph of the Complaint. Defendants therefore lack sufficient information or
2 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
3 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
4 the study for its actual language and text. Any attempt to characterize the study is denied.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 105. Defendants state that allegations in this paragraph of the Complaint regarding Merck
7 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and
8 therefore no response is required. To the extent that a response is deemed required, Plaintiff
9 fails to provide the proper context for the allegations in this paragraph of the Complaint
10 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
11 sufficient information or knowledge to form a belief as to the truth of such allegations and,
12 therefore, deny the same. Defendants state that the referenced study speaks for itself and
13 respectfully refer the Court to the study for its actual language and text. Any attempt to
14 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of
15 the Complaint.

16 106. Defendants state that allegations in this paragraph of the Complaint regarding Merck
17 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and
18 therefore no response is required. To the extent that a response is deemed required, Plaintiff
19 fails to provide the proper context for the allegations in this paragraph of the Complaint
20 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack
21 sufficient information or knowledge to form a belief as to the truth of such allegations and,
22 therefore, deny the same. Defendants state that the referenced study speaks for itself and
23 respectfully refer the Court to the study for its actual language and text. Any attempt to
24 characterize the study is denied. Defendants state that the referenced article speaks for itself
25 and respectfully refer the Court to the article for its actual language and text. Any attempt to
26 characterize the article is denied. Defendants deny the remaining allegations in this paragraph
27 of the Complaint.

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1 107. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants deny the allegations in this
3 paragraph of the Complaint.

4 108. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 109. Defendants state that allegations in this paragraph of the Complaint are not directed
8 toward Defendants, and therefore no response is required. To the extent that a response is
9 deemed required, Defendants state that the referenced article speaks for itself and respectfully
10 refer the Court to the article for its actual language and text. Any attempt to characterize the
11 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 110. Defendants deny the allegations in this paragraph of the Complaint.

13 111. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
18 remaining allegations contained in this paragraph of the Complaint.

19 112. Defendants deny any wrongful conduct and deny the allegations contained in this
20 paragraph of the Complaint.

21 113. Defendants deny any wrongful conduct and deny the allegations contained in this
22 paragraph of the Complaint.

23 114. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
28 paragraph of the Complaint.

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115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants admit that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

117. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by

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1 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
3 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
4 United States to be prescribed by healthcare providers who are by law authorized to prescribe
5 drugs in accordance with their approval by the FDA. Defendants deny the remaining
6 allegations in this paragraph of the Complaint.

7 118. Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
12 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
13 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
15 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
16 United States to be prescribed by healthcare providers who are by law authorized to prescribe
17 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a
18 prescription medication which is approved by the FDA for the following indications: (1) for
19 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of
20 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the
21 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps
22 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic
23 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for
24 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age
25 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 119. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which at all times was adequate and comported with applicable standards of care and law.
3 Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding
4 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
5 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
6 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
7 allegations in this paragraph of the Complaint.

8 120. Defendants state that Celebrex® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
13 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
15 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
16 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the
17 United States to be prescribed by healthcare providers who are by law authorized to prescribe
18 drugs in accordance with their approval by the FDA. Defendants deny the remaining
19 allegations in this paragraph of the Complaint.

20 121. Defendants state that Celebrex® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,
23 which at all times was adequate and comported with applicable standards of care and law.
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
25 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for
28 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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1 United States to be prescribed by healthcare providers who are by law authorized to prescribe
2 drugs in accordance with their approval by the FDA. Defendants deny the remaining
3 allegations in this paragraph of the Complaint.

4 122. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 123. Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 124. Defendants deny the allegations in this paragraph of the Complaint.

17 125. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 126. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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1 127. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
4 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
5 paragraph of the Complaint.

6 128. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
11 remaining allegations in this paragraph of the Complaint.

12 129. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® are and were adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 130. Defendants state that Celebrex® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Celebrex® are and were adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
23 the study for its actual language and text. Any attempt to characterize the study is denied.
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
25 the Complaint.

26 131. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
28 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

1 effective when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® are and were adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
5 remaining allegations in this paragraph of the Complaint.

6 **Response to First Cause of Action: Negligence**

7 132. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
8 Complaint as if fully set forth herein.

9 133. Defendants state that this paragraph of the Complaint contains legal contentions to
10 which no response is required. To the extent that a response is deemed required, Defendants
11 admit that they had duties as are imposed by law but deny having breached such duties.
12 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
13 FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 134. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is required. To the extent that a response is deemed required, Defendants
20 admit that they had duties as are imposed by law but deny having breached such duties.
21 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
22 FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 135. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint, including all subparts.

5 136. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 137. Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 138. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
26 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
27 paragraph of the Complaint.

28

1 139. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
4 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
5 paragraph of the Complaint.

6 140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 141. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Second Cause of Action: Strict Liability**

11 142. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
12 Complaint as if fully set forth herein.

13 143. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of
16 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
18 with their approval by the FDA. Defendants admit that, during certain periods of time,
19 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
20 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
22 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and
23 consumers without substantial change from the time of sale. Defendants deny the remaining
24 allegations in this paragraph of the Complaint.

25 144. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 145. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
8 remaining allegations in this paragraph of the Complaint.

9 146. Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the
14 remaining allegations in this paragraph of the Complaint, including all subparts.

15 147. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
22 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
23 remaining allegations in this paragraph of the Complaint.

24 148. Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
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1 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
2 remaining allegations in this paragraph of the Complaint.

3 149. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
11 remaining allegations in this paragraph of the Complaint.

12 150. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 151. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-
23 approved prescribing information, which was at all times adequate and comported with
24 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
25 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
26 paragraph of the Complaint.

27 152. Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 153. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint.

15 155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
16 damage, and deny the remaining allegations in this paragraph of the Complaint.

17 156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
18 damage, and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to Third Cause of Action: Breach of Express Warranty**

20 157. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 158. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants admit that they provided FDA-approved

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1 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
2 this paragraph of the Complaint.

3 159. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants admit that they provided FDA-approved
10 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and
11 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

12 160. Defendants admit that they provided FDA-approved prescribing information regarding
13 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this
14 paragraph of the Complaint.

15 161. Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
20 the Complaint.

21 162. Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint.

27 163. Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

164. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

167. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

168. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

169. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 170. Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 171. Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 172. Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny the remaining allegations in this paragraph of the Complaint.

16 173. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants admit that they provided FDA-approved
23 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in
24 this paragraph of the Complaint.

25 174. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,
28

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Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

175. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that they breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

176. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

177. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

178. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

179. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

180. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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181. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

182. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

183. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

184. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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185. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

186. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

187. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

188. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 189. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint.

13 190. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
20 remaining allegations in this paragraph of the Complaint.

21 191. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 192. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 193. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

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Response to Sixth Cause of Action: Unjust Enrichment

194. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

195. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

196. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

197. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

198. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

1 199. Defendants are without knowledge or information sufficient to form a belief as to the
 2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
 3 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
 4 effective when used in accordance with its FDA-approved prescribing information. Defendants
 5 state that the potential effects of Celebrex® were and are adequately described in its FDA-
 6 approved prescribing information, which was at all times adequate and comported with
 7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
 8 remaining allegations in this paragraph of the Complaint.

9 200. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
 10 damage, and deny the remaining allegations in this paragraph of the Complaint.

11 **Response to Seventh Cause of Action:**

12 **State Consumer Fraud and Deceptive Trade Practices Acts**

13 201. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
 14 Complaint as if fully set forth herein.

15 202. Defendants are without knowledge or information sufficient to form a belief as to the
 16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
 17 Celebrex® and, therefore, deny the same. Defendants state that this paragraph of the Complaint
 18 contains legal contentions to which no response is required. To the extent that a response is
 19 deemed required, Defendants admit that they had duties as are imposed by law but deny having
 20 breached such duties. Defendants deny the remaining allegations in this paragraph of the
 21 Complaint.

22 203. Defendants are without knowledge or information sufficient to form a belief as to the
 23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
 24 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
 25 effective when used in accordance with its FDA-approved prescribing information. Defendants
 26 state that the potential effects of Celebrex® were and are adequately described in its FDA-
 27 approved prescribing information, which was at all times adequate and comported with
 28

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1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
2 remaining allegations in this paragraph of the Complaint.

3 204. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
11 paragraph of the Complaint.

12 205. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this
15 paragraph of the Complaint.

16 206. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
19 remaining allegations in this paragraph of the Complaint.

20 207. Defendants deny any wrongful conduct and deny the remaining allegations in this
21 paragraph of the Complaint.

22 208. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 209. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 210. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.
28

211. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

212. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for Relief,” including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

1 **Third Defense**

2 3. At all relevant times, Defendants provided proper warnings, information, and
3 instructions for the drug in accordance with generally recognized and prevailing standards in
4 existence at the time.

5 **Fourth Defense**

6 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
7 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
8 knowledge at the time the drug was manufactured, marketed, and distributed.

9 **Fifth Defense**

10 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
11 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

12 **Sixth Defense**

13 6. Plaintiff's action is barred by the statute of repose.

14 **Seventh Defense**

15 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily
16 negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by
17 Plaintiff should be diminished accordingly.

18 **Eighth Defense**

19 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
20 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
21 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
22 liable in any way.

23 **Ninth Defense**

24 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
25 intervening causes for which Defendants cannot be liable.

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Tenth Defense

10. Any injuries or expenses incurred by Plaintiff was not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Virginia and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and,

1 therefore, constitute protected commercial speech under the applicable provisions of the United
2 States Constitution.

3 **Thirty-eighth Defense**

4 38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
5 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
6 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
7 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
8 Amendment of the United States Constitution, the Commerce Clause of the United States
9 Constitution, and the Full Faith and Credit Clause of the United States Constitution, and
10 applicable provisions of the Constitutions of the States of Virginia and California. Any law,
11 statute, or other authority purporting to permit the recovery of punitive damages in this case is
12 unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks
13 constitutionally sufficient standards to guide and restrain the jury's discretion in determining
14 whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that
15 it failed to provide adequate advance notice as to what conduct will result in punitive damages;
16 (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied
17 with applicable law, or conduct that was not directed, or did not proximately cause harm, to
18 Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and
19 proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory
20 damages, if any; (5) permits jury consideration of net worth or other financial information
21 relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial
22 court in post-verdict review of any punitive damages awards; (7) lacks constitutionally
23 sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to
24 satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v.*
25 *Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S.
26 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut.*
27 *Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

1 **Fifty-second Defense**

2 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
3 common law gives deference to discretionary actions by the United States Food and Drug
4 Administration under the Federal Food, Drug, and Cosmetic Act.

5 **Fifty-third Defense**

6 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
7 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
8 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
9 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
10 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
11 and with the specific determinations by FDA specifying the language that should be used in the
12 labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the
13 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
14 United States.

15 **Fifty-fourth Defense**

16 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
17 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

18 **Fifty-fifth Defense**

19 55. Defendants state on information and belief that the Complaint and each purported cause
20 of action contained therein is barred by the statutes of limitations contained in California Code
21 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
22 as may apply.

23 **Fifty-sixth Defense**

24 56. Defendants state on information and belief that any injuries, losses, or damages suffered
25 by Plaintiff was proximately caused, in whole or in part, by the negligence or other actionable
26 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against
27 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

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Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiff's claims for punitive damages are barred, in whole or in part, by Virginia Code § 8.01-38.1.

Fifty-ninth Defense

59. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses, or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

1 November 9, 2007

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By: : _____/s/_____

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

November 9, 2007

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